

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Richard L. Vandlen et al. Serial No.: To Be Assigned Filed: December 17, 2001 For: STRUCTURE, PRODUCTION AND USE OF HEREGULIN 2 LIGANDS	Group Art Unit: To Be Assigned Examiner: To Be Assigned <div style="border: 1px solid black; padding: 5px;"> <p style="text-align: center; font-size: small;">CERTIFICATION UNDER 37 CFR 1.10</p> <p style="font-size: x-small;">This is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated below and is addressed to the Assistant Commissioner of Patents, Washington, D.C. 20231.</p> <p style="font-size: x-small;">Express Mail No. EL 889 332 581 US</p> <p style="text-align: right;">December 17, 2001</p> <p style="text-align: right;"><i>Anna Kan</i></p> <p style="text-align: right;">Anna Kan</p> </div>
---	---

JC675 U.S. PTO
 10/022609
 12/17/01

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents
 Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☒ **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☐ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified). A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in prior application Serial No. 08/035,430, filed March 22, 1993, Serial No. 08/330,161 filed October 25, 1994 (now U.S. patent no. 5,834,229), Serial No. 08/440,401 (now U.S. patent 5,856,110), filed May 12, 1995 and Serial No. 09/173,480 filed October 14, 1998 and relied upon in this application for an earlier filing date under 35 USC §120.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-0" (nucleotide) and "BLAST Results B-1 - B-0" (protein) on the PTO

Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p).

Respectfully submitted,

GENENTECH, INC.

By: _____

Wendy M. Lee

Reg. No. 40,378

Telephone No. (650) 225-1994



09157

PATENT TRADEMARK OFFICE

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark OfficeAtty Docket No.
P0712C5Serial No.
To Be Assigned

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant
Vandlen et al.Filing Date
17 Dec 2001Group
To Be Assigned

U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	4,683,195	28.07.87	Mullis et al.			
	* 2	4,882,275	21.11.89	Klagsburn			07.04.86
	* 3	4,968,603	06.11.90	Slamon et al.			
	* 4	5,169,837	08.12.92	Lagarde et al.			28.03.91
	* 5	5,237,056	17.08.93	Fischbach			
	* 6	5,367,060	22.11.94	Vandlen et al.			
	* 7	5,464,751	07.11.95	Greene et al.			
	* 8	5,578,482	26.11.96	Lippman et al.			
	* 9	5,594,114	14.01.97	Goodearl et al.			23.09.94
	*10	5,641,869	24.06.97	Vandlen et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	No
	*11	505,148	23.09.92	EPO				
	*12	WO 91/15230	17.10.91	PCT				
	*13	WO 91/18921	12.12.91	PCT				
	*14	WO 92/00595	03.04.92	PCT				
	*15	WO 92/12174	23.07.92	PCT				
	*16	WO 92/18627	29.10.92	PCT				
	*17	WO 93/22339	11.11.93	PCT				
	*18	WO 93/22424	11.11.93	PCT				

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	*19	Bargmann et al., "Multiple Independent Activations of the neu Oncogene by a Point Mutation Altering the Transmembrane Domain of p185" <u>Cell</u> 45:649-657 (June 6, 1986)
	*20	Benveniste et al., "Purification and characterization of a human T-lymphocyte-derived glial growth-promoting factor" <u>Proc. Natl. Acad. Sci.</u> 82:3930-3934 (1985)
	*21	Brockes et al., "Glial growth factor-like activity in Schwann Cell tumors" <u>Annals of Neurology</u> 20:317-322 (1986)
	*22	Brockes et al., "Purification and preliminary characterization of a glial growth factor from the bovine pituitary" <u>Journal of Biological Chemistry</u> 255(18):8374-8377 (1980)
	*23	Brockes, "Assay and isolation of glial growth factor from the bovine pituitary" <u>Methods in Enzymology</u> 147:217-225 (1987)
	*24	Cohen, J.A. et al., "Expression of the neu proto-oncogene by Schwann Cells during peripheral nerve development and Wallerian degeneration" <u>J. Neuroscience Res.</u> 31:622-634 (1992)
	*25	Davis et al., "Isolation and characterization of a neu protein-specific activating factor from human ATL-2 cell conditioned medium" <u>Biochem. & Biophys. Res. Comm.</u> 179(3):1536-1542 (1991)
	*26	Davis et al., "Platelet-derived growth factors and fibroblast growth factors are mitogens for rat Schwann Cells" <u>Journal of Cell Biology</u> 110:1353-1360 (1990)

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark OfficeAtty Docket No.
P0712C5Serial No.
To Be Assigned

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant
Vandlen et al.Filing Date
17 Dec 2001Group
To Be Assigned

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- | | |
|-----|---|
| *27 | De Corte et al., "A 50 kDa protein present in conditioned medium of COLO-16 cells stimulates cell spreading and motility, and activates tyrosine phosphorylation of Neu/HER-2, in human SK-BR-3 mammary cancer cells" <u>J. Cell Science</u> 107:405-416 (1994) |
| *28 | Dobashi et al., "Characterization of a neu/c-erbB-2 protein-specific activating factor" <u>Proc. Natl. Acad. Sci.</u> 88:8582-8596 (1991) |
| *29 | Falls et al., "ARIA, a protein that stimulates acetylcholine receptor synthesis, is a member of the Neu ligand family" <u>Cell</u> 72:801-815 (1993) |
| *30 | Fitzgerald et al., "Characterization and Sequence Analysis of the Human Ornithine Decarboxylase Gene" <u>DNA</u> 8(9):623-634 (1989) |
| *31 | Gray et al., "Nucleotide sequence of epidermal growth factor cDNA predicts a 128,000-molecular weight protein precursor" <u>Nature</u> 303:722-725 (1983) |
| *32 | Groenen et al., "Structure-Function Relationships for the EGF/TGF- α Family of Mitogens" <u>Growth Factors</u> 11:235-257 (1994) |
| *33 | Hoffman, Michelle, "New Clue Found to Oncogene's Role in Breast Cancer" <u>Science</u> 256:1129 (1992) |
| *34 | Holmes et al., "Identification of Heregulin, A Specific Activator of p185erbB2" <u>Science</u> 256:1205-1210 (May 22, 1992) |
| *35 | Hudziak et al., "p185HER2 Monoclonal Antibody Has Antiproliferative Effects In Vitro and Sensitizes Human Breast Tumor Cells to Tumor Necrosis Factor" <u>Molecular & Cellular Biology</u> 9(3):1165-1172 (Mar 1989) |
| *36 | Kimura et al., "Structure, expression and function of a schwannoma-derived growth factor" <u>Nature</u> 348:257-260 (1990) |
| *37 | Kokai et al., "Phosphorylation process induced by epidermal growth factor alters the oncogenic and cellular neu (NGL) gene products" <u>Proc. Natl. Acad. Sci USA</u> 85:5389-5393 (1988) |
| *38 | Kunisada et al., "Sequence Organization of Repetitive Sequences Enriched in Small Polydisperse Circular DNAs from HeLa Cells" <u>J. Mol. Biol.</u> 198:557-565 (1987) |
| *39 | Lemke & Brockes, "Identification and purification of glial growth factor" <u>J. Neurosci.</u> 4(1):75-83 (1984) |
| *40 | Lupu et al., "Direct interaction of a ligand for the erbB2 oncogene product with the EGF receptor and p185erbB2" <u>Science</u> 249:1552-1555 (1990) |
| *41 | Lupu et al., "Purification and Characterization of a Novel Growth Factor from Human Breast Cancer Cells" <u>Biochemistry</u> 31:7330-7340 (1992) |
| *42 | Lupu et al., "Purification of a novel growth factor that binds exclusively to the erbB-2 receptor protein and induces cellular responses" <u>Proc. Am. Assoc. Cancer Res.</u> 32:abst. no. 297, p. 50 (1991) |
| *43 | Maniatis et al. <u>Molecular Cloning: A Laboratory Manual</u> , 1st edition, New York: Cold Spring Harbor Lab Press, Chapter 12, pps. selected pages (1982) |
| *44 | Marchionni et al., "Glial growth factors are alternatively spliced erbB2 ligands expressed in the nervous system" <u>Nature</u> 362:312-318 (1993) |
| *45 | Nagata et al., "Solution structure of the epidermal growth factor-like domain of heregulin- α , a ligand for p180erbB-4" <u>EMBO J.</u> 13(15):3517-3523 (1994) |
| *46 | Nosoh et al. <u>Protein Stability and Stabilization through Protein Engineering</u> , New York: Ellis Harwood pps. 26, 27, 55, 56, 62, 143, 180, (1991) |

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P0712C5	Serial No. To Be Assigned
				Applicant Vandlen et al.	
				Filing Date 17 Dec 2001	Group To Be Assigned
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)					
*47	"Paper No. 7" (Amendment A) from file history of USSN 08/096,277 (now US Patent 5,578,482)				
*48	"Paper No. 8" (Office Action) from file history of USSN 08/096,277 (now US Patent No. 5,578,482)				
*49	Peles et al., "Isolation of the Neu/HER-2 Stimulatory Ligand: A 44 Kd Glycoprotein That Induces Differentiation of Mammary Tumor Cells" <u>Cell</u> 69(1):205-216 (1992)				
*50	Pohlenz et al., "The Human VK Locus, Characterization of Extended Immunoglobulin Gene Regions by Cosmid Cloning" <u>J. Mol. Biol.</u> 193:241-253 (1987)				
*51	Sliwkowski et al., "Coexpression of erbB2 and erbB3 Proteins Reconstitutes a High Affinity Receptor for Heregulin" <u>Journal of Biological Chemistry</u> 269(20):14661-14665 (May 20, 1994)				
*52	Tarakhovsky et al., "A 25 kDa polypeptide is the ligand for p185Neu and is secreted by activated macrophages" <u>Oncogene</u> 6(12):2187-2196 (1991)				
*53	Trachtenberg et al., "Schwann cell apoptosis at developing neuromuscular junctions is regulated by glial growth factor" <u>Nature</u> 379:174-177 (1996)				
*54	Wen et al., "Neu differentiation factor: a transmembrane glycoprotein containing an EGF Domain and an Immunoglobulin Homology Unit" <u>Cell</u> 69(3):559-572 (1992)				
*55	Xu et al. <u>Eighty-Second Annual Meeting of the American Association for Cancer Research Proceedings</u> 32:260 (Abstract No. 1544 1991)				
*56	Yarden et al., "Experimental approaches to hypothetical hormones: detection of a candidate ligand of the neu protooncogene" <u>Proc. Natl. Acad. Sci. USA</u> 86:3179-3183 (1989)				
*57	Yarden, "Biochemical Analysis of the Ligand for the neu Oncogenic Receptor" <u>Biochemistry</u> 30:3543-3550 (1991)				
Examiner				Date Considered	
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.					